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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,761

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Alan Crossman

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11/27/2009

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EXAMINER

JAVANMARD, SAHAR

ART UNIT

PAPER NUMBER

1627

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,761	Applicant(s) CROSSMAN ET AL.	
	Examiner SAHAR JAVANMARD	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15, 19 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 15, 19 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/6/09; 9/1/09; 10/23/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on July 20, 2009. Claim(s) 14-15, 19, and 25-27 are pending and examined herein.

Response to Arguments

Applicant's arguments with respect to the 103(a) rejection of claims 14-15, 19, and 25-27 as being unpatentable over Chenard (EP 0900568 A2) in view of Skradski (*Epilepsia*, 2000) in further view of Dursun et al. (*Canadian Journal of Psychiatry*, 2000) have been fully considered but are not persuasive as Applicant is arguing based on amended claims.

Applicant argues that Chenard discloses a large number of compounds as being suitable AMPA receptor antagonists but fails to teach or suggest the use of compound I as an agent for treating dyskinesia (chorea or dystonia).

Examiner respectfully notes that Chenard was employed to demonstrate that it is known in the art to employ AMPA receptor antagonists to treat dyskinesia. Examiner employs Skradski to demonstrate that topiramate is also an AMPA receptor antagonist and can be among the choice of compounds used to treat dyskinesia.

Applicant alleges that "Skradski states that one cannot use their studies to reach definitive conclusions about the mechanisms of action of topiramate (see page S45, summary, right column, lines 7 and 8 of Skradski)." This is not

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persuasive. In fact Skradski states that this study provides additional support for the antagonistic role that topiramate plays at the AMPA receptor. Thus Examiner maintains the position that the teachings of Skradski would motivate one in the art to also employ topiramate as an AMPA antagonist in the treatment of dyskinesia as taught by Chenard.

Applicant further argues that Chenard's definition of dyskinesia conflicts with what is taught in the art. This is not persuasive. According to the website "answers.com" (made of record previously), the definition of dyskinesia is defined as "excessive abnormal movements that are involuntary." Further, the reference defines the different categories of dyskinesia to include chorea, dystonia, myoclonus, tremor, etc. Thus, in light of this definition, the term dyskinesia as defined by Chenard does not appear to conflict with the art as Applicant alleges. Therefore, it is Examiner's opinion that based on the foregoing arguments and rejections made of record, the instant claims are deemed unpatentable over the cited art.

The 103(a) rejection is hereby maintained and modified as necessitated by amendment in the FINAL office action below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the

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subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-15, 19, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chenard (EP 0900568 A2) in view of Skradski (*Epilepsia*, 2000) in further view of Dursun et al. (*Canadian Journal of Psychiatry*, 2000).

Chenard teaches the administration of AMPA receptor antagonists for the treatment of dyskinesia which results as a side effect of dopamine agonist therapy given as a therapeutic regimen for Parkinson's disease (page 2, lines 5-7).

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Chenard teaches that after a period of chronic administration of dopamine agonist therapy to treat Parkinson's disease motor abnormalities such as choreatic dyskinesia and dystonia arise (page 2, lines 21-25).

Chenard teaches that the term dyskinesia means any abnormal or uncontrollable movement including **chorea**, tremor, **dystonia**, myoclonus and tic, among others (page 10, lines 50-51).

Chenard teaches dopamine agonist therapies include the administration of one or more of the following: L-dopa, bromocriptine, pergolide, ropinirole, cabergoline, and lisuride (page 10-11, [0014]).

Chenard does not teach topiramate as the AMPA receptor antagonist.

Skradski teaches that topiramate possesses AMPA receptor antagonist properties (abstract; discussion).

Dursun discloses a study whereby a 29-year-old male diagnosed with chronic paranoid schizophrenia is treated with clozapine and responds positively to the medication. The patient however develops some side effects including myoclonic jerks in both hands, arms, and shoulders, in addition to excessive weight gain (column 1, paragraph 1). The same patient is then administered topiramate which showed improvement in his mood and complete improvement of his myoclonic jerks (column, paragraph 3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed an AMPA receptor antagonist as a treatment for dyskinesia as taught by Chenard and also employed topiramate. The motivation,

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provided by Skradski, teaches that topiramate possesses AMPA receptor antagonist properties. Thus one would expect with a reasonable degree of success that the treatment of dyskinesia with one AMPA receptor agonist over another would be equally successful, in the absence of unexpected results. Additionally, one would be further encouraged that the employment of topiramate in the treatment of dyskinesia would be successful in light of the teachings of Dursun. As discussed above, Dursun teaches that topiramate is able to improve myoclonic jerks in the patient (which also arises as a side effect of a drug). As set forth on record, Chenard teaches that myoclonus is also encompassed by dyskinesia. Thus as one of ordinary skill in the art would expect with a reasonable degree of success that topiramate would be able to treat the abnormal or uncontrollable movements associated with dyskinesia.

Conclusion

Claims 14-15, 19, and 25-27 are not allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory

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period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAHAR JAVANMARD whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627